In the Supreme Court of the United States

OCTOBER TERM, 1973

No. 72-1593

LABEL, INC., PETITIONER

v.

SHERWIN GARDNER, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

MEMORANDUM FOR THE RESPONDENTS IN OPPOSITION

Petitioner seeks review of a decision holding that the Federal Food, Drug, and Cosmetic Act does not authorize the promulgation of a substantive rule requiring manufacturers and distributors of standardized foods to list all ingredients on the label of their products.

1. By petition filed on February 25, 1971, petitioner requested the Food and Drug Administration to issue the following substantive regulation:

> For the purposes of promoting honesty and fair dealing in the interest of the consumer, all food manufacturers and distributors must list on the label, all ingredients which are contained in their product.[1]

[1] The proposed rule is partially redundant since ingredient labeling of nonstandardized foods is already required by Section 403(i) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 343(i).

The Commissioner of Food and Drugs published the petition in the Federal Register on May 12, 1971, and invited comments by interested persons on the proposed rule and his authority to issue it. 36 Fed. Reg. 8738. After the comments were reviewed and evaluated, the Commissioner published an order in the Federal Register of March 10, 1972, denying the petition on the ground that he lacked the authority to promulgate the requested regulation. 37 Fed. Reg. 5131.[2]

Petitioner sought review of the agency order in the United States Court of Appeals for the District of Columbia Circuit. The court of appeals affirmed *per curiam* (Pet. App. 1a-3a).

2. The decision below is correct and the petition for certiorari raises no question warranting further review.

Petitioner asserts that Section 701(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), authorizes the issuance of the substantive rule requested. Section 701(a) provides:

> The authority to promulgate regulations *for the efficient enforcement of this Act*, except as otherwise provided in this section, is hereby vested in the Secretary. [Emphasis added.]

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[2] At the same time, because of his agreement with the objective of the petition and the significant consumer interest involved, the Commissioner promulgated a statement of policy encouraging all manufacturers, packers and distributors of standardized foods voluntarily to make such disclosures. 21 C.F.R. 3.88. Additionally, the Commissioner recommended legislation authorizing the agency to require full ingredient labeling of standardized foods. A bill to that effect was introduced in the ninety-second Congress, H.R. 14641, and reintroduced in the ninety-third Congress, S. 1451 and H.R. 5642.

This Section empowers the Secretary to issue substantive rules to construe, interpret and apply existing statutory provisions. It does not, however, authorize him "to alter or add to" the regulatory scheme adopted by Congress. *United States* v. *Antikamnia Co.*, 231 U.S. 654, 666.

The Federal Food, Drug and Cosmetic Act designates two classes of foods—standardized and nonstandardized —and establishes different ingredient labeling requirements for each.[3] These requirements are set forth in Section 403 of the Act, 21 U.S.C. 343, which provides in pertinent part:

> A food shall be deemed to be misbranded—
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> * * * * *
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> (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients * * * present in such food.
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> * * * * *
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> (i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there

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[3] Standardized foods are those for which regulations have been promulgated by the Commissioner establishing "a reasonable definition and standard of identity, a reasonable standard of quality and/or reasonable standards of fill of container." Section 401 of the Act, 21 U.S.C. 341. All other foods are nonstandardized.

> be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient * * *.

In *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 230, this Court analyzed Section 403 of the Act, explaining:

> Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. * * * Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products can be effectively maintained," * * * and to require informative labeling only where * * * the food did not purport to comply with a standard, or where the regulations permitted optional ingredients and required their mention on the label. [Citations omitted.]

Congress, in the Federal Food, Drug, and Cosmetic Act, could have required full ingredient labeling of all foods, but it adopted instead the "standard of identity" regulatory scheme embodied in Sections 403(g) and (i). See *Quaker Oats Co., supra,* 318 U.S. at 232. Given the language and purpose of the statute, the Commissioner may not by administrative rulemaking substitute his judgment for that of the legislature. Only Congress, not the Commissioner, may revise the law. Accordingly, the Commissioner properly concluded that he lacked the authority to issue the regulation requested.

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

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JULY 1973.